Announcement of Federal Funding Opportunity

Summary

I. GENERAL INFORMATION

A. Program Name: Defense Advanced Research Project Agency – Deep Bleeder Acoustic Coagulation(DBAC)

B. Funding Opportunity Number: DARPA05-01DBAC

C. Agency Name: Defense Advanced Research Projects Agency
3701 North Fairfax Drive
Arlington, VA 22203-1714

D. Agency Contact(s): Mr. Thomas McCreery

1. Questions related to the Program, proposal format, or required documentation may be addressed to DARPA at:

Phone:	703-248-1517
Fax:	703-516-7360
E-mail:	tmccreery@darpa.mil
Mail:	Defense Advanced Research Projects Agency 3701 North Fairfax Drive Arlington, VA 22203-1714

E. Anticipated Instrument Type(s): Contracts, Grants/Cooperative Agreements and Other Transaction Agreements.

F. Catalog of Federal Domestic Assistance (CFDA) Number(s): 12.420; Military Medical Research and Development.

G. Award/Regulatory Approval: Once an award is made, the applicant may not use, employ, or subcontract for the use of any human subjects, human anatomical substances/cadavers, or laboratory animals without written permission from the applicable USAMRMC regulatory office. The applicable USAMRMC regulatory office will forward these written approvals directly to the applicant.

II. FUNDING OPPORTUNITY DESCRIPTION

Extremity wounds predominate on today's battlefield because the torso is protected by the ballistic vest. Blood loss from extremity wounds is the number one cause of preventable battlefield death today (Infantry Magazine, 2004). Loss of blood causes soldiers to enter hemorrhagic shock. There are three stages of shock due to loss of blood: non-progressive shock

in which the body can respond and survive without treatment; progressive shock, in which shock becomes progressively worse and death will occur without treatment; and irreversible shock, which leads to death. The goal of the DBAC program is to stop bleeding quickly enough to prevent the transition from non-progressive shock to progressive shock, which occurs when the soldier loses 25% of his blood volume.

III. ELIGIBILITY INFORMATION

Applicants: Independent investigators at all academic levels (or equivalent) are eligible to submit proposals. All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution.

Institutions: Eligible institutions include for-profit, non-profit, public, and private organizations.

Other Eligibility Criteria: Please see the Full Text of Program Announcement description for details regarding duplicate submissions, applications from Historically Black Colleges and Universities/Minority Institutions (HBCU/MI), and administrative compliance issues.

IV. PROPOSAL PREPARATION AND SUBMISSION INFORMATION

A. Proposal Information: Applicants must submit an original (paper) proposal consisting of Volumes I and II, five (5) paper copies and an electronic copy on one of the following types of approved fixed media: a single CD-ROM; a single 100 Megabyte (MB) Iomega Zip disk; or a single 3.5 inch High Density MS-DOS formatted 1.44 MB diskette. Further instructions are provided in Section IV.

B. Submission Date and Time: Deadline: July 14, 2005. Proposals must be received by 1600 EST (4:00 PM EST) at Schafer Corporation, 3811 N. Fairfax Drive, Arlington, VA 22203, ATTN: Mr. Larry Dobbs/DARPA05-01DBAC/Document Control

V. PROPOSAL EVALUATION

Evaluation of the DBAC proposals will be performed using the following criteria, which are listed in descending order of relative importance:

a) Scientific and technical merit
b) Offeror qualifications
c) Cost realism

VI. AWARD ADMINISTRATION INFORMATION

A. Award Notices and Administrative Requirements: Details of award notification procedures and administrative requirements including regulatory documents (Certificate of

Environmental Compliance, Research Involving Human Subjects and/or Anatomical Substances, Research Involving Animals, and Safety Program Plan) can be found in the Full Text of Program Announcement.

B. Reporting Requirements: Performers will provide monthly status reports, quarterly reports and a final report at the end of each phase.

Full Text of Program Announcement

I. GENERAL INFORMATION

A. Program Name: Defense Advanced Research Project Agency – Deep Bleeder Acoustic Coagulation (DBAC)

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Mail:	Defense Advanced Research Project Agency 3701 North Fairfax Drive Arlington, VA 22203-1714

E. Anticipated Instrument Type(s): This DARPA extramural research program will be performed through the award of contracts/grants/cooperative agreements and other transaction agreements. More information on these funding instruments may be obtained by request from:

Fax:	301-619-2195
E-mail:	kathy.robinson@det.amedd.army.mil
Mail:	Director US Army Medical Research Acquisition Activity ATTN: MCMR-AAA-P 820 Chandler Street Fort Detrick, MD 21702-5014

F. Catalog of Federal Domestic Assistance (CFDA) Number 12.420: Military Medical Research and Development.

G. Award/Regulatory Approval: Once an award is made, the applicant may not use, employ, or subcontract for the use of any human subjects, human anatomical substances, or laboratory animals without written permission from the applicable USAMRMC regulatory

office. The applicable USAMRMC regulatory office will forward these written approvals directly to the applicant.

II. FUNDING OPPORTUNITY DESCRIPTION

1. PROPOSER INFORMATION:

The Defense Advanced Research Projects Agency (DARPA) often solicits research efforts through the Broad Agency Announcement (BAA). This announcement however is being solicited as a Program Announcement (PA). The PA is announced in the Federal Business Opportunities (FedBizOpps), a website (http://www.fedbizopps.gov/) sponsored by the General Services Administration (GSA). The following information is for parties interested in responding to DARPA05-01DBAC, Deep Bleeder Acoustic Coagulation.

It is the policy of DARPA to treat all proposals as competitive information and to disclose the contents only for the purposes of evaluation. The Government evaluation team will consist of Government personnel from DARPA and other Government agencies. For this solicitation, non-Government advisors, who have signed appropriate non-disclosure and conflict of interest statements, may assist in the proposal administration and review process when their particular expertise is required; however, they will not participate in the final source selection process.

DARPA requests that all parties interested in participating in this PA register their organization by providing a principal point of contact, phone number, fax, and email to DARPA05-01DBAC@darpa.mil with the subject line: "Deep Bleeder Acoustic Coagulation POC INFORMATION".

2. PROGRAM BACKGROUND AND GOALS:

2.1. Military Operational Need

Extremity wounds predominate on today's battlefield because the torso is protected by the ballistic vest. Blood loss from extremity wounds is the number one cause of preventable battlefield death today (Infantry Magazine, 2004). Loss of blood causes soldiers to enter hemorrhagic shock. There are three stages of shock due to loss of blood: non-progressive shock in which the body can respond and survive without treatment; progressive shock, in which shock becomes progressively worse and death will occur without treatment; and irreversible shock, which leads to death. The goal of the DBAC program is to stop bleeding quickly enough to prevent the transition from non-progressive shock to progressive shock, which occurs when the soldier loses 25% of his blood volume.

In order to treat these extremity wounds the source of the bleeding must be found and the bleeding must be stopped. In the DBAC program, treatment is defined as a three step process. Step one is detection of flowing blood. Step two is localization of the precise source of the blood flow. The third and final step is to coagulate the blood to stop the bleeding. Soldier's lives are in danger from wounds that cause progressive shock over a period of hours (slow bleeders) as well as the wounds that cause progressive shock in 60 seconds or less (fast bleeders). Slow bleeders and fast bleeders present distinctly different challenges to treatment.

The threat from slow bleeders is that soldiers may continue to function after being wounded, unaware of continuing blood loss from smaller, oozing punctures. Over time, this situation can result in the onset of progressive and then irreversible shock. This program aims to prevent progressive shock that would otherwise take place within 8 hours of injury. The challenge for these slow bleeders is both to detect their presence and to localize them to allow coagulation.

The challenge with a fast bleeding wound is to coagulate the blood before the soldier enters progressive shock. This part of the DBAC program is focused on stopping bleeding that can cause progressive shock in the parts of the body not protected by the ballistic vest. The femoral artery is the largest vessel not protected by the ballistic vest and has the highest flow rate. A soldier with a puncture that is equal to or larger than the diameter of the femoral artery loses enough blood to cross the progressive shock threshold within 30 seconds of being wounded. This short window of opportunity means that the treatment must be administered by the soldiers on the scene, not after evacuation or the arrival of trained medical personnel.

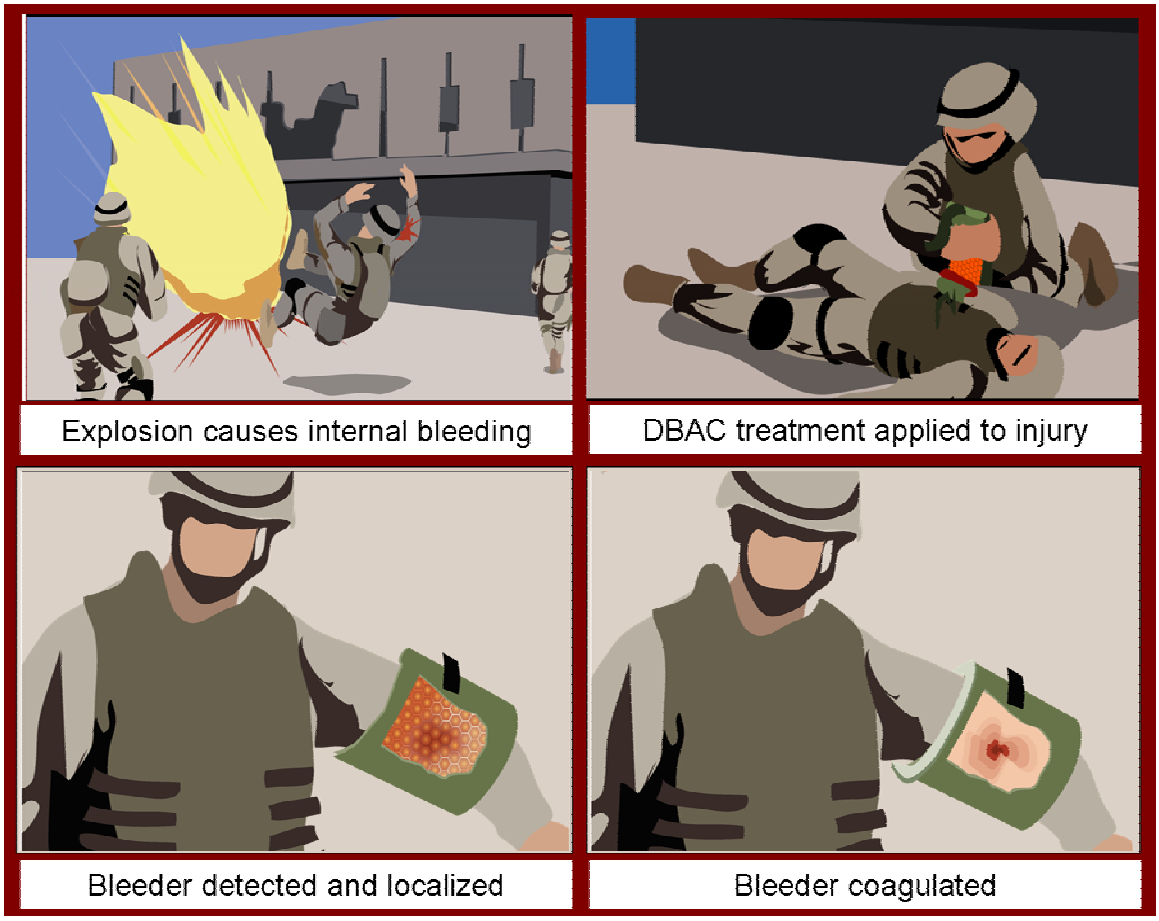

Figure 1: DBAC Concept of Operations

The DBAC program will develop a system that operates in a fully automated manner on the battlefield, as shown notionally in Figure 1. In particular, it must be able to detect, localize, and coagulate the full range of life-threatening bleeders without requiring a soldier to interpret an image displayed by the device. The system must be capable of treating everyone from small female soldiers to large male soldiers. The power used to coagulate the bleeding can not

cause damage to the skin or the tissue surrounding the wound. The cuff weight is limited because the system needs to be usable on tissue that is burned or damaged by blast. Finally, the system must be portable enough to take to the battlefield which limits the total system weight and the system volume.

2.2. Technical Approach

The DBAC system must be completely non-invasive: no injections of drugs or other materials may be used. A soldier must be able to place the device around a wounded area without knowing precisely where the bleeder is (or even whether any bleeding is occurring); therefore, the device must not rely on any prescribed orientation with respect to the bleeder. DARPA anticipates that a conformal wrap-around device, as shown in Figure 2, that operates as a stationary tool will satisfy this requirement better than a smaller handheld device that must be moved around the body. The DBAC notional approach, as shown in Figure 2, uses multiple transducers to detect, localize, and then coagulate the bleeder without causing damage to the skin or the tissue surrounding the bleeder.

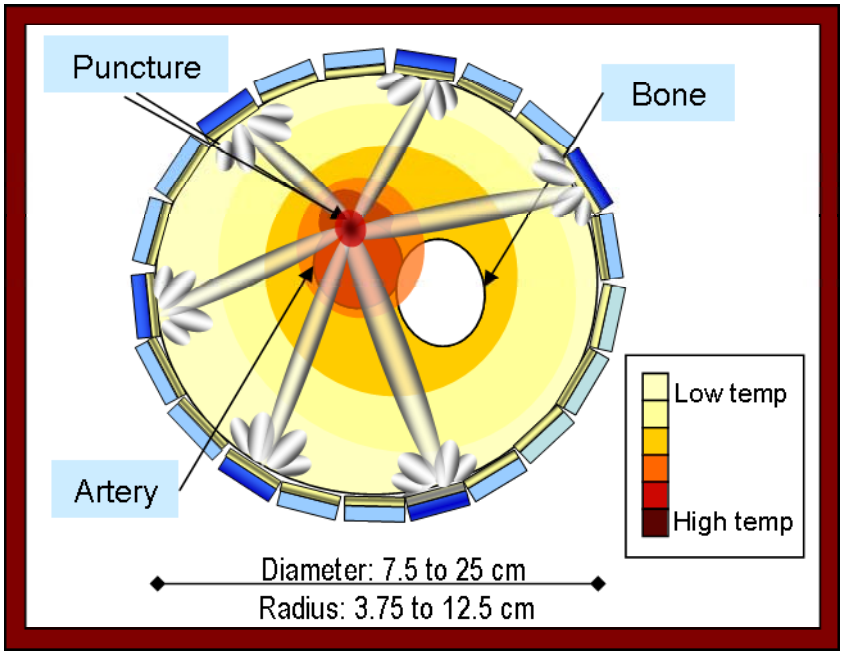

Figure 2: Use of diversely spaced ultrasound transducers to coagulate bleeder with high intensity focused ultrasound (HIFU) while maintaining safe temperatures in tissue outside of coagulation area.

This BAA is written with a focus on an acoustic approach to detect, localize, and coagulate bleeders. This focus is due to ultrasound's potential to non-invasively detect and localize bleeders using Doppler and two-dimensional imaging information, and to coagulate using high intensity focused ultrasound (HIFU) to heat the blood to the coagulation temperature. Other potential approaches have been evaluated. Radio frequency (RF) coagulation of the bleeding is possible; however the RF electrode needs to be in contact with the bleeder and thus requires invasive placement of an RF needle source into the tissue around the wound.

Furthermore, RF alone can not detect or localize the bleeding and would need to be used with another imaging modality such as ultrasound.

Microbubbles could be administered that contain agent to promote clotting; however, this would require personnel with sufficient medical training to place an intravenous line in a patient with low blood pressure and low blood volume.

Proposers with alternative solutions that meet the need to detect, localize, and coagulate bleeding non-invasively on the battlefield without the involvement of skilled medical personnel are encouraged to arrange meetings with the DBAC program manager and to propose to this BAA. Proposers with an alternative non-acoustic approach must be prepared to discuss the nature of the testbed needed to validate and verify their alternative solution.

2.3. Technical Specifications

The DBAC system must be able to cover the full range of life-threatening bleeders from the fast bleeder, which causes a soldier to enter progressive shock in 30 seconds, to the slow bleeder, which causes progressive shock in 8 hours. It must be able to stop these bleeders in the full range of soldier body types on the battlefield. These program goals lead to the technical specifications laid out in Table 1. These specifications must be met in the cuff that is built in Phase I.

Quantity	Definition	Most Challenging Problem	Specification
MDV	Minimum detectable velocity	Slow bleeder in small vessel	3 cm/sec
MSR	Minimum structure resolution	Slow bleeder in large vessel	0.06 cm
MPD	Minimum power deposition	Fast bleeder in large vessel	8900 W/cm^2
MTT	Maximum tissue temperature	Minimum power deposition	43º C
MCS	Minimum cuff size	Man's thigh	40 cm x 80 cm
MRC	Minimum radius of curvature	Woman's bicep	3.75 cm
MDP	Minimum depth of penetration	Man's thigh	12.5 cm
MCW	Maximum cuff weight	Treating burned tissue	3 kg

Table 1: DBAC Phase I Specifications.

The minimum detectable velocity is the velocity of the slowest bleeder that can cause a 25% blood loss in 8 hours. (MDV in Figure 3). The slowest flow that leads to this level of blood loss occurs in a 0.15 cm artery (e.g. the Dorsalis Pedis in the foot). Blood will be flowing out of this vessel at a velocity of 3 cm/s. This sets the minimum detectable velocity (MDV) for the DBAC program.

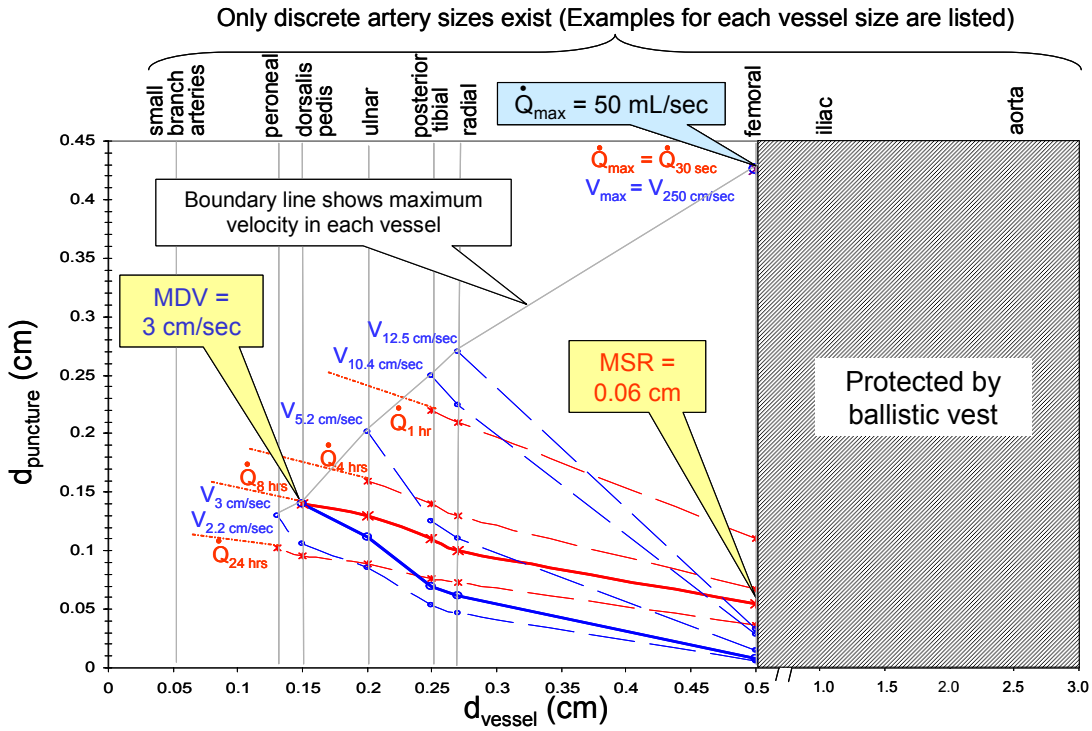

Figure 3: Flow rate and velocity contours in vessels not protected by the ballistic vest.

The system must also localize the puncture that is the source of the blood flow. The localization challenge arises from the smallest puncture that can result in progressive shock in 8 hours. This occurs for the largest vessel not protected by the ballistic vest (MSR in Figure 3). This sets the minimum spatial resolution (MSR) for the DBAC program as 0.6mm.
The coagulation challenge is to coagulate the largest puncture in the largest vessel unprotected by the ballistic vest that will result in 25% blood loss. As shown in Figure 3, this level of blood loss occurs in the femoral artery within 30 seconds after the artery is severed. The temperature of the blood in the artery must be raised 9ºC to achieve this seal through blood coagulation. The minimum power deposition (MPD) required to achieve this 9ºC temperature increase is 8900 W/cm^2.

This power needed for coagulation must be deposited without causing thermal damage to the skin or to the tissue surrounding the bleeder. Skin and tissue are damaged when they are heated beyond 43° C. This sets the maximum tissue temperature (MTT).

The cuff must be large enough to wrap around the thigh of a large male soldier. This leads to the minimum cuff size (MCS) of 40 cm x 80 cm.

The need to treat bleeders in the thigh of a large male soldier drives the minimum depth penetration (MDP) of 12.5 cm.

The cuff must also be sufficiently flexible to wrap around an adult female bicep radius of 3.75 cm. This is the minimum radius of curvature (MRC) for the program.

Soldiers with life-threatening bleeding often are also suffering from burns and blast damage. In order to minimize the strain and pressure caused by the cuff on the damaged tissue, the cuff can weigh no more than 3 kg. This is the maximum cuff weight (MCW).

The technical specifications listed in Table 2 pertain to the fully automated fieldable prototype device and must be met by the end of Phase III.

Quantity	Definition	Most Challenging Problem	Specification
MFBTT	Maximum fast bleeder treatment time	Fast bleeder in large vessel	30 seconds
MSBTT	Maximum slow bleeder treatment time	Slow bleeder	10 minutes
System weight	Total system weight including cuff and batteries	Batteries	25 kg
System volume	Total system size including cuff and batteries		Standard issue rucksack volume

Table 2: Additional DBAC Specifications to be completed in Phase III.

The system must be capable of detecting, localizing, and coagulating the full range of bleeders rapidly enough to save a soldier's life. This allows only 30 seconds to stop a femoral artery bleeder and thus we have set the maximum fast bleeder treatment time (MFBTT) to 30 seconds. In the case of slow bleeders more time is available before the wound becomes life threatening; for these the maximum slow bleeder treatment time (MSBTT) is set to 10 minutes.

The system must be capable of being fielded on the battlefield by a single soldier. This sets the system weight requirement, including the cuff and batteries, of no more than 25 kg, and the system volume of no larger than a standard issue rucksack.

3. Programmatics and Deliverables

3.1. Program Overview

The DBAC program will develop a portable, light-weight, non-invasive, automated system for the detection, localization, and coagulation of deep bleeders that is operable by minimally trained personnel in the combat environment. Phase I will cover designing and building the ultrasound transducer cuff described in §2 and demonstrating it at the DBAC testbed (see §4). During Phase II, performers will design and develop the detection, localization, and coagulation algorithms and use these algorithms to demonstrate control of the ultrasound transducer cuff developed in Phase I at the DBAC testbed with a human in the loop. In Phase III, an automated system will be developed that can achieve the program goals without a human in the loop; this full system will be demonstrated in vitro and in vivo at the DBAC testbed.

3.2 DBAC Phase I

During the 18 month development phase, performers will build the ultrasound transducer cuff and develop device performance and biophysical models.

The prototype system will be completely controlled by a human operator. The prototype DBAC device will be brought to the testbed in the sixth quarter of the phase. The device will be tested for the required detection, localization, and coagulation performance. The performer will need to demonstrate that the device meets all the specifications in Table 1, using a phantom at the DBAC testbed.

The device performance model will model device characteristics including acoustic crosstalk, surface heating of the device, output power levels, speed of detection and localization including scan time and processing time, and frequency range. The biophysical model will simulate the effects of detection, localization, and coagulation on tissue, blood within vessels, and blood flowing out of punctured vessels. The coagulation portion of the model will simulate the effects of input power on coagulation including tissue temperature and the effects of varying the duty cycle. The model will include inputs for tissue motion, bone reflection, and the effect of metal fragments within the tissue on the treatment process. The model will be validated using data from the in vitro testing at the DBAC testbed.

3.3 Phase I Deliverables

The first quarterly report must include the completed system design and the final plan for the construction of the DBAC device. Approval of this material must be completed before the performer begins construction of the cuff device.

The second and third quarterly reports will describe the progress on construction of the DBAC device and development of the performance and biophysical models. The modeling progress report must describe how the models are addressing the topics in §3.2.

The fourth quarterly report must include the plan to test the device at the testbed in coordination with the testbed team. Modeling and simulation results for device performance and the interaction of the device with biological tissue will be presented.

The fifth quarterly report will describe the status of the cuff device system, performance results collected in the performer's laboratory, and readiness for independent validation and verification (IV&V) testing. The performer will provide an evaluation of any health and safety issues that will need to coordinate with the testbed team.

The Phase I final report will include the performance of the system at the testbed and a prediction of the performance of the planned DBAC system based on the validated performance and biophysical models. Scientific and technical reports will be required for all measurements and modeling results, subsystem, component, and other technology developed as part of this effort. The final report will include an updated statement of work and budget for Phase II.

In anticipation of animal testing in Phase II the proposers must submit an animal care and use protocol that has been approved by their institution's animal care and use committee (IACUC) as an appendix to their final report.

3.4 DBAC Phase II

During the 15 month Phase II, performers will develop bleeder detection, localization, coagulation algorithms, and an automatable cuff control system, and integrate them with the cuff device. The performance and biophysical models developed in Phase I will be used to evaluate the trades (processing speed vs. precision, depth penetration vs. resolution, power deposition vs. tissue temperature, and duty cycle vs. coagulation efficiency) needed to develop the automatable control system and algorithms. Based on the approved animal care and use protocol, performers will conduct in vivo experiments to determine the effect of motion artifacts and other physiological challenges on the algorithms and to test and refine the performance and biophysical models.

The detection, localization, and coagulation algorithms and the control system must each be developed so as to enable the complete system to be automated in Phase III. The control system for the device will include software to evaluate the progress of the detection, localization, and coagulation steps. This software will produce signals that can be connected to a display to allow for indications that the system is operating and whether or not coagulation has been successful. The performers will demonstrate at the DBAC testbed that the system can achieve detection, localization, and coagulation with a human decision maker in the loop.

3.5 Phase II Deliverables

The first quarterly report must include a test plan that shows when the in-house in vivo testing will be conducted and how this data will be used to modify the algorithms and control system.

The second and third quarterly reports will describe the progress on development of the detection, localization, and coagulation algorithms and the control system and a description of their performance.

The fourth quarterly report will describe the detection, localization, and coagulation results from the in vivo testing conducted in-house by the performer.

As part of their Phase II final report, performers must present experimental data from the in-house in vivo testing and the in vitro results at the DBAC testbed. The report will include data on how algorithm effectiveness differed between in vitro and in vivo testing and the changes that will be made to the algorithms and models to improve in vivo efficacy. The final report must include a design for an automated, fieldable prototype system that operates on batteries. The final report must also include an updated statement of work, including a development plan, and budget for Phase III.

3.6 DBAC Phase III

During the 15 month Phase III the performer will develop a fieldable prototype system that operates on batteries. This system will use the prototype cuff device that was developed in Phase I.

The fieldable prototype system will be automated and capable of detecting and localizing the minimum bleeder size, tracking the movement of the site of bleeding based on tissue and patient movement, coagulating the bleeder, and determining completion of coagulation without a human decision maker in the loop.

The prototype system will include a display that reports when the bleeder has been detected and localized, and whether or not the coagulation has been successful. The display that is developed will not be an anatomical image but will be an easily interpreted signal such as a red or green light.

The performer will demonstrate that the system meets the MFBTT and MSBTT in vivo and at the testbed. The testbed team will test the system performance in vitro and the system must demonstrate the ability to detect, localize, and coagulate the bleeder without a human decision maker in the loop. In addition, the cuff weight, system weight, and system volume will be evaluated by the testbed team. The system will also be demonstrated in vivo using protocols developed by the US Army Institute of Surgical Research (USAISR) at the DBAC testbed location. This demonstration will be carried out using the fieldable prototype system that meets the cuff and system weight and system volume requirements and is battery powered.

3.7 Phase III Deliverables

The first quarterly report must include an updated development plan for the fieldable prototype system.

The second and third quarterly reports will describe the progress in the development of the prototype system, including the automated control system and the display.

In the fourth quarter the performer will deliver the fieldable prototype system to the testbed.

As part of their final report, performers will provide a detailed description of the in vivo and testbed results. Users' manuals (manufacture, operations, maintenance, and safety) will be provided and documentation of any testing carried out. Additional documentation will be provided as is required for a Premarket Approval (PMA) submission.

3.8 Reporting Requirements (All Phases)

Performers will provide monthly status reports, due within two weeks of the end of each month; quarterly reports, due every quarter (at the time of the Government quarterly review, if applicable); and a final report, due at the end of each phase. The monthly status report will briefly summarize the progress of the research activities during the previous month, including major accomplishments as well as any significant difficulties that have been experienced or are expected. It will identify any aspects of the work that are ahead of or behind schedule. It will track the expenditures of funds, by month and cumulatively, and report actual or anticipated

cost overruns or underruns. The quarterly reports will provide a more detailed description of all significant progress since the previous quarterly report, describing results, status, and conclusions to date. It also affords the opportunity to suggest modifications to the previously agreed upon statement of work (SOW), based on the results to date. The final report for each phase of the program will be a cumulative, stand-alone document that describes the work of the entire phase leading up to it. Performers are also responsible for providing Scientific and Technical Reports (STARs) as applicable for their work funded under this effort, including for all: measurements taken (including the experimental methods, test conditions, and uncertainty estimates); models developed (including the underlying physical basis for the models, assumptions, and experimental data used for calibration or validation); simulation results (including a description of the models/codes used, and the conditions simulated – initial and boundary conditions); formulations developed (including the processes used to make the formulations); and subsystems (design and prototypes). STARs are due at the end of each Phase.

All reports must be delivered in both print format and editable electronic format; the performer may recommend a preferred format for each deliverable, but the Government will have final approval. Quarterly and final reports will consist of both a written report and a shorter briefing to be presented orally; monthly reports will consist of only a written document (no oral presentation required).

With the exception of any financial information or other exceptions negotiated as described in §7.1.9, all deliverables may be released to outside organizations, both Government and non-Government.

4. DBAC TEST BED

The DBAC program will develop a testbed to carry out independent validation and verification (IV&V) of the performance of the devices developed in the program (§3).

4.1 Testbed Description

Multiple test fixtures or phantoms that simulate biological detection, localization, and coagulation challenges will be developed and operated by the testbed team to determine whether the performers' devices meet the detection, localization, and coagulation goals. All phantoms will be made using tissue-mimicking materials to simulate the in vivo anatomy and physiology. Phantoms used to evaluate the MDV and MSR goals will be produced that allow the generation of precise blood flows in a range of vessel diameters and puncture sizes. Coagulation phantoms will be instrumented so that the MPD and the MTT can be measured in the blood mimic (e.g. normal saline), in the proximal tissue-mimicking material, and at the simulated skin surface, as shown in Figure 2. The testbed team will also evaluate all devices for MCS, MRC, MDP, and MCW.

In Phase III, the testbed team will work with the US Army Institute of Surgical Research to establish animal test protocols that will be used to evaluate the fieldable prototype systems.

4.2 Non-Disclosure Agreements

Successful performers under this BAA will be expected to interact with the testbed personnel. These interactions will necessitate the sharing of technical and performance information about

their Government-funded activities. Performers should be prepared to reveal, to the extent necessary for this purpose and under appropriate non-disclosure agreements, the product developed as part of their work under this BAA.

4.3 Health and Safety Information

Successful performers under this BAA will be required to supply the testbed's risk management personnel with the appropriate health and safety information regarding the materials and methods required to conduct IV&V testing at the testbed. All documentation, such as health and safety levels and Material Safety Data Sheets (MSDS), must be provided by the performer prior to demonstration at the testbed.

4.4 Testbed Location

DARPA will develop a testbed in coordination with the Stanford University Cardiovascular Biomechanics Research Laboratory. This testbed will be operated by Stanford University personnel for DARPA. Proposers should include travel costs to Stanford, CA, in their proposals

5. DBAC FUNDING

No specific funding target is provided. Best value to the government will be a selection criterion..

6. DBAC SCHEDULE

The anticipated schedule is given below. Changes to the solicitation dates will be sent to all organizations that have registered their interest in this BAA. Changes to the post-award dates will be communicated directly to the performers.

6.1 Solicitation Schedule

DATE	***EVENT***
26 May 2005	FedBizOpps announcement published.
17 June 2005	Registration ends for Pre-proposal Conference.
21 June 2005	Pre-proposal Conference.
14 July 2005	Proposals due.
July 2005	Source selection.
August 2005	Contract negotiations.
August/September 2005	Kickoff meetings.

Table 3. Tentative schedule of events and deadlines associated with BAA DARPA05-01DBAC.

6.2 Performer Schedule (Major Milestones)

Phase I:

4Q FY05 Kickoff Meetings

1Q FY06 DBAC device build plan due

1Q FY07 Demonstrate that the cuff system meets the cuff specs (MDV, MSR, MPD, MTT, MCS, MRC, MDP, and MCW)

1Q FY07 Performance and biophysical models due

1Q FY07 Phase I final report

Phase II:

2Q FY07 Detection, localization, and coagulation algorithm plan due

2Q FY07 IACUC approved Animal Use Protocol due

2Q FY08 Demonstrate that the detection, localization, and coagulation algorithms are able to detect localize and coagulate deep internal bleeders at the specs required in Phase I

2Q FY08 Phase II final report

Phase III:

3Q FY08 Automated detection, localization, and coagulation system plan due

3Q FY09 Demonstrate that the integration of the detection, localization, and coagulation algorithms with the device produce a fully automated battery powered system that meets the MFBTT, MSBTT, and system weight, system volume, and the requirements met in Phase I

3Q FY09 Phase III final report and users' manuals

In addition, there will be quarterly reviews with the DARPA Program Manager and Contracting Officer. Teleconferences and other meetings will be scheduled as required.

III. AWARDS

The Government reserves the right to select for award all, some, or none of the proposals received in response to this announcement. Awards may be traditional FAR/DFARS contracts, grants, cooperative agreements, and/or Other Transaction Agreements. The Government is seeking participation from the widest number of offerors. All responsible sources may submit

a proposal, which will be considered by the Government. Historically Black Colleges and Universities (HBCU) and Minority Institutions (MI) are encouraged to submit proposals or to team with others in submitting proposals; however, no portion of this PA is set-aside for HBCU and MI participation, due to the impracticality of reserving discrete or severable areas of technology for exclusive competition among these entities.

IV. ELIGIBILITY INFORMATION

1. Applicants

All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution as defined below.

2. Institutions

Eligible institutions include for-profit, non-profit, public, and private organizations. Examples include universities, colleges, hospitals, laboratories, companies, and agencies of local, state, and federal governments.

V. PROPOSAL PREPARATION AND SUBMISSION INFORMATION

A. ADMINISTRATIVE INFORMATION AND PROPOSAL SUBMISSION

Information announcing and updating this PA is published on the Federal Business Opportunities website http://www.eps.gov/. In addition, an electronic copy of the FedBizOpps announcement can be found on the World Wide Web at http://www.darpa.mil/spo under "Solicitations." If the offeror does not have access to the World Wide Web, a request for the PIP can be emailed to DARPA05-01DBAC@darpa.mil (subject line: REQUEST PIP); or faxed to (703) 807-4946, (Attn: DARPA05-01DBAC PIP Request); or mailed in written form to Schafer Corp, Suite 400 (Attn: DARPA05-01DBAC PIP Request), 3811 North Fairfax Drive, Arlington, VA 22203. The message must include the name of the POC, phone number, fax number, and an address to use for surface mail delivery if email is not available. Offerors without access to electronic means of communication should be aware of the increased response time required by surface mail.

This PIP, along with the Federal Business Opportunities announcement, constitutes a Broad Agency Announcement (BAA) as contemplated in FAR 6.102 (d)(2)(i). Prospective offerors must refer to this PIP before submitting a proposal. This announcement does not commit the Government to pay for any response preparation cost. The cost of preparing proposals in response to the PA is not considered an allowable direct charge to any other contract. However, it may be an allowable expense as specified in FAR 31.205-18.

Other information is available as described below.

1. SOLICITATION REGISTRATION

All parties interested in participating in this PA must register their interest by providing the following information for their organization: a principal point of contact, phone number, fax, and email. This information should be emailed to DARPA05-01DBAC@darpa.mil with the subject line "REGISTER." DARPA will make available to all who register a complete list of the registered organizations and the contact information, unless any organization specifically requests not to be included on such a list.

2. SOLICITATION WEBSITE

At the time of registration, each organization will be provided a password for accessing the website for this solicitation. This website will contain regularly updated information about this solicitation, as necessary. It will include a list of Frequently Asked Questions (FAQ) and their answers.

3. PRE-PROPOSAL CONFERENCE

DARPA will host a Pre-proposal Conference on 21 June 2005 at Schafer Corporation, 3811 N. Fairfax Dr, Suite 400, Arlington, VA 22203. Each organization that plans to attend this meeting must indicate their intention by email to DARPA05-01DBAC@darpa.mil, with the subject line, "PRE-PROPOSAL CONFERENCE." In addition, each organization must provide the names of all planned attendees (using the same email address). Additional instructions will be provided to those who register. Registration to attend this meeting must be received no later than 17 June 2005. Applicants who miss this deadline will be accepted on a space-available basis.

4. CONTACTING DARPA

Technical, contractual, or administrative questions will be answered if they are submitted in writing until one week before proposals are due. They may be submitted through the website after registration or emailed to DARPA05-01DBAC@darpa.mil with the subject line "DARPA05-01DBAC QUESTION." These are the preferred modes for submitting questions. For those without access to electronic communication, faxed or written questions will be accepted at the addresses listed at the beginning of section V. A. Regardless of how questions are sent to DARPA, the question and its answer (without the name of originator) will be appended to the FAQ file on the solicitation website for viewing by all registered organizations.

In addition, the DARPA program manager will meet privately during the week of 27 June to 1 July 2005 with those bidders who request a private meeting. The purpose of these meetings is not to provide proposal advice to prospective bidders. It is to provide clarification about the intent of this PA, especially to offerors who will propose solutions fundamentally different from the acoustic approach, for whom this PIP will not provide full guidance. Topics discussed during these meetings will be considered proprietary and not be made available to others. Meetings may be requested through the solicitation website, using the subject line "MEETING REQUEST." The duration of the meeting may be limited to one hour, depending on the number of prospective bidders who request such a meeting. The location of the meetings will

be announced at the pre-proposal conference. Bidder's who miss this meeting window may submit written questions as described in the preceding paragraph.

B. PROPOSAL PREPARATION INSTRUCTIONS

The Government anticipates that awards will be made during the fourth quarter of the Government fiscal year 2005. Offerors should submit multiple year proposals that span all phases of the program, beginning with a base period of 18 months for Phase I, and follow-on options of 15 months for Phase II and 15 months for Phase III. All data an offeror deems pertinent to a proposal should be submitted with the proposal. Proposals will consist of two volumes: Volume I – Technical Proposal, and Volume II – Cost Proposal. Proposals must be submitted in both print and electronic form, as described in Section IV. Proposals will be prepared in the following format: single sided, 8.5 x 11 inches, in at least 12 point type, single spaced with margins not less than one inch. Pages must be numbered sequentially.

Questions regarding proposal submission should be directed to one of the points of contact listed in Section V A. Offerors are advised that only contracting officers are legally authorized to contractually bind or otherwise commit the Government.

Proposal Forms (Appendices 3-11) should be completed and included as part of the submission package. Electronic and scanned signatures are acceptable. Full proposals may be submitted without protocols for human and animal use (Appendicies 9 & 10). However, protocols with required institutional approvals must be submitted not later than 60 days after award to ensure continuation of payment. The contracting office may grant exceptions in situations where human and/or animal use are not expected to begin until after the first year of the research project. In such cases, a time frame for submission of the appropriate protocols should be established during discussions/negotiations, prior to award.

1. VOLUME I – TECHNICAL PROPOSAL

Volume I will be no longer than 40 pages in length, not including the sections excluded below. Foldouts are counted as a single page and must be no larger than 11 x 17 inches with no more than five foldouts allowed in the proposal. Only the first 40 pages of Volume I proposals will be evaluated. Proposals with fewer than the maximum number of pages are highly encouraged. Clarity in describing the work to be carried out will be used during the evaluation process as an important indicator of the ability of the proposer to plan and carry out the work.

The following outline describes the minimum requirements for Volume I and must appear in clearly marked form in the order indicated.

A. Cover Page *
B. Table of Contents *
C. Executive Summary
D. Technical Approach
E. Statement of Work
F. Schedule and Milestones *
G. Deliverables

* Items not included in Volume I page limit

H. Description of Resources and Facilities
I. Offeror capabilities and Experience
J. Key Personnel Summary
K. Ownership of Products
L. Organizational Conflict of Interest *
M. Appendix A *
N. Quad chart showing performer approach

Cover Page (not included in the Volume I page limit)

The Cover Page must include the following information in the order indicated:

a)	PA number:	DARPA05-01DBAC
b)	PA title:	Deep Bleeder Acoustic Coagulation
c)	Proposal Title:	(as selected by offeror)
d)	Volume I – Technical Proposal	
e)	Prime Offeror:	(name of prime)
f)	Subcontractors:	(listed, if applicable)
g)	Technical Contact:	(name, address, phone/fax, electronic mail address)
h)	Administrative Contact:	(name, address, phone/fax, electronic mail address)
i)	Type of Business:	(large business, small disadvantaged business, other small business, HBCU or MI, other education, or nonprofit)

Executive Summary

The executive summary will provide an overview of the proposed system and a brief statement of the work required to develop the approach into a working system (through the end of Phase III). Any outstanding features that the offeror believes distinguish the proposal should be clearly and succinctly identified here.

Technical Approach

a) Prototype cuff device approach: The proposal must include a notional design for the hardware capable of meeting all the technical requirements shown in Table 1. This design must include a description of the array approach and the method used to manufacture the ultrasound array. The proposal must provide a description of the frequency and power range of the proposed device and show how this relates to meeting the specifications in Table 1. Critical technical issues for success of the device must be identified; including any long-lead-time materials needed, novel materials that must be fabricated, interconnect and crosstalk issues. Predictions of performance should be supported by data and/or modeling and simulation to the extent possible.

b) Modeling and simulation approach: The proposal must include a description of the device performance modeling approach and the biophysics model approach, and how the two models will be linked together once developed. The description of the modeling approaches must include the concepts that the models will be based on and the modeling approach that is planned to achieve the modeling goals described in §3.2.

c) Algorithm development approach: The proposal must describe the concepts that will be used to develop the detection, localization, and coagulation algorithms that will be needed in Phases II and III of the DBAC program.

d) Control system approach: The approach must include a control system concept that will be used in Phase I. The approach must include a notional plan as to how the algorithms developed in Phase II will be used to provide inputs to the control system for the cuff device. The approach must also include how the control system can integrate a display to indicate that the bleeder has been detected and localized, and whether or not the coagulation has been successful in Phase III.

e) Logistics: The offeror must include a preliminary plan as to how they will achieve the system weight limit of 25 kg including the cuff weight limit of 3 kg, the system size limit of a rucksack, and the final battery based system in the later phases.

f) Manufacturability: The offeror must describe the manufacturability of their proposed device including information on how it could be produced in large scale, whether automated production is possible, and an estimate of how long it takes to produce each device.

g) Robustness: The proposal must include an evaluation of the robustness of their proposed device for use on the battlefield. Potential challenges include transport on rough roads in a military vehicle, high speed transport in a small water craft, and use in airborne operations.

h) Safety: The proposal must include an evaluation of the safety of the class of the materials and components included in the proposed barrier system. This evaluation should include MSDS information for the system components.

Statement of Work (SOW)

The offeror will provide a SOW written in plain English, describing the proposed plans to carry out the work under this PA. The SOW will build on the technical approach described in Section V.B and must describe the specific activities the bidders propose in order to carry out the work described in Section V.B. The SOW will be divided into tasks of the bidder's choosing; those tasks should be readily identifiable with the work described in Section V.B. In developing their SOWs, bidders should include experimental, theoretical, and modeling/simulation elements as appropriate.

The Phase I plan must be specific and detailed. The Phase II and Phase III plans may be outlined more broadly, since detailed versions will be delivered at the end of each preceding phase.

During the work under this PA, it is expected that the SOW will evolve. It will be periodically reviewed and updated with Government approval.

Schedule and Milestones (not included in the Volume I page limit)

Proposals will include a schedule for the tasks in the SOW. It will include a graphic illustration showing the major milestones in the SOW arrayed against the proposed time for each task.

Deliverables

Proposals will include a list of deliverables, correlated with the corresponding SOW tasks. At a minimum, offerors should include the deliverables listed in Section 3.

Resources and Facilities

Offerors will identify all resources to be used in carrying out this work, and will specify the availability of those resources for this work. When offerors plan to subcontract with outside organizations not part of the proposal, these organizations, their capabilities, and their commitment to providing the needed support must be clearly identified. Any interactions with or agreements with U.S. Government facilities for this purpose must also be identified.

Offeror Capabilities and Experience

Offerors will describe their capabilities and experience in the area of diagnostic and therapeutic ultrasound that indicate ability to carry out the proposed work.
Offerors will describe any experience in manufacturing similar or related products to the DBAC device.

Key Personnel Summary

Certain skilled, experienced professional and/or technical personnel are essential for successful completion of the work to be performed under this contract. These "Key Personnel" will be identified by name in the proposal, and must include at least one person from each subcontracting organization, as well as the proposed manager of the overall effort. They will be described concisely in a few pages, listing a summary of the qualifications and relevant past efforts of each person, the critical contributions they are expected to make to the effort, their clearance level, and their proposed level of effort. The contractor agrees that such personnel will not be removed from work on this contract or replaced without compliance with the Key Personnel Requirement described in Section VII F.

Ownership of Products

The U.S. Government will have ownership of all reports, data, models, equipment, synthesis plans and prototypes that result from this effort. The Government may choose to disseminate some of the reports and results publicly and may discuss them at conferences and at other public and private meetings. The results may form the basis for subsequent BAA, PA, or other solicitations from DARPA or other Government organizations.

The Government expects to retain, at a minimum, Government Purpose Rights (GPR) to all intellectual property (IP) resulting from this effort, including technical data and synthesis plans and device designs, as set forth in DFARS 252.227-7013 and DFARS 252.227-7014. The Government will entertain negotiations for exceptions from GPR, under limited circumstances, as set forth under DFARS 252.227-7013(b) (4) and DFARS 252.227-7014(b) (4). The proposal should include a summary of any previously existing proprietary claims to results, prototypes, or systems that will play a role in this work, and describe what aspects of existing systems will not be divulged to the Government. If there are no proprietary claims, this section will consist of a statement to that effect. Any agreement for work resulting from this PA will require continual supplementation of said proprietary claims summary. In addition, and where appropriate, Volume II of each proposal will have attached to it the information required by DFARS 252.227-7017, IDENTIFICATION AND ASSERTION OF USE, RELEASE, OR DISCLOSURE RESTRICTIONS (JUN 1995) and/or DFARS 252.227-7028 (JUN 1995) TECHNICAL DATA OR COMPUTER SOFTWARE PREVIOUSLY DELIVERED TO THE GOVERNMENT.

Organizational Conflict of Interest (not included in the Volume I page limit)

Each proposal will contain a section to comply with the following requirements. All awards made under this PA are subject to the provisions of the Federal Acquisition Regulation (FAR) Subpart 9.5, Organizational Conflict of Interest. All offerors and proposed subcontractors must affirmatively state whether they are supporting any DARPA technical office(s) through an active contract or subcontract. All affirmations must state which office(s) the offeror supports and identify the prime contract number. Affirmations will be furnished at the time of proposal submission. All facts relevant to the existence or potential existence of organizational conflicts of interest, as that term is defined in FAR 9.501, must be disclosed. This disclosure will include a description of the action the offeror has taken, or proposes to take, to avoid, neutralize or mitigate such conflict. If the offeror believes that no such conflict exists, then it will so state in this section.

Only those offerors whose proposals are expected to result in contract award will be required to submit a completed and signed copy of "Representations, Certifications, and other Statements by Offerors or Quoters." This document is not required for the submission of a proposal unless specifically requested. Offerors are notified that this document is frequently updated and any offeror selected for award may be requested to submit an updated "Representations, Certifications, and Other Statements by Offerors or Quoters."

Appendix A (not included in the Volume I page limit)

a) PERSONNEL: The proposal will include a list of all personnel identified to work on the proposed activity. This list will include "Key Personnel," as well as other important prime and subcontractor personnel. A concise resume will be provided for "Key Personnel" as well as short summaries for other personnel, describing their qualifications, current clearance level, and the amount of effort committed to this work for each contract year. Key Personnel are subject to the conditions set forth in Section V B.

b) ASSOCIATE CONTRACTOR AGREEMENTS: Proposals will list all sub-contractor and other agreements existing or planned to support this work, including a description of the status of each such agreement.

c) GOVERNMENT FURNISHED PROPERTY/EQUIPMENT: If any portion of the research is predicated upon the use of Government owned resources of any type that is not included in the proposed budget, the offeror will specifically identify the property or other resource required, the date the property or resource is required, the duration of the requirement, the source from which the resource is required, if known, and the impact on the research if the resource cannot be provided. If no Government Furnished Property is required to conduct the proposed research, this section will consist of a statement to that effect.

2. VOLUME II – COST PROPOSAL

Cost proposals have no page-length limitations; however, offerors are requested to keep cost proposals to approximately 15 pages. The electronic version of the Cost Proposal must be contained on the same CD-ROM, Zip disk, or diskette that contains the Technical Proposal, and any electronic spreadsheets must be submitted in a format usable in Microsoft Excel.

The Cost Proposal must contain the following sections, in the order listed:

a) Cover Page
b) Table of Contents
c) Budget Summary
d) Budget Details
e) Details of any cost sharing by the offeror (if proposed)

In addition, each cost proposal will contain a section that identifies the offeror's Taxpayer's Identification Number (TIN), DFARS 204.7202-3; Corporate and Government Entity (CAGE) code, DFARS 204.7202-1; and Contractor Establishment Code (CEC), DFARS 204.7202-2. The codes provided will be those of the offeror and not of the principal place of performance, if the two are different.

Cover Page

The Cover Page is the same as that for Volume I/Technical Proposal (see Section V B), except that item d) will read "Volume II – Cost Proposal."

Budget Summary

Proposals must include a separate budget summary for each program phase. The summary costs for Phase I will be the result of a detailed financial analysis that is provided separately; the summary costs for Phases II and II should be the best current estimate, given that the final scope of work for each Phase depends on the results of the preceding Phase.

The budget summary must show, by phase: the cost for each task identified in the SOW of the Technical Proposal, including the manpower levels of effort (labor hours and cost) by task; cost of equipment, travel, G&A, and other expenses. Costs for team members or other subcontractors must be clearly identified under the appropriate tasks, and the net amount proposed for each organization must also be separately and clearly labeled.

Budget Details

The cost to carry out Phase I will be specified in detail, showing the information below by Government fiscal year (October through September). Similarly detailed information will be provided for later Phases as one of the deliverables for the preceding Phases.

Labor hours for each labor category, divided into the tasks and subtask areas identified in the SOW, Volume I. Optional tasks/subtask areas must be listed individually and priced separately.

1. Personnel (name or designation, rate in dollars per labor hour, and percent time on project).
2. Total cost by task/subtask identified in the SOW/Volume I.
3. Total cost by labor category, with subtotals for each task.

4. Proposed contractor-acquired equipment, itemized with costs or estimated costs. An explanation of any estimating factors, including their derivation and application, must be provided. Include under "Budget Details" a brief description of the procurement method to be used.
5. Travel costs.
6. Materials costs.
7. Other direct/indirect costs.
8. Subcontractor costs (net)
9. Any other information important for supplementing the Budget Summary for Phase I.

Note that each subcontractor must provide a cost breakdown for Phase I that is similarly detailed. This cost breakdown may be submitted as part of the prime contractor proposal, or it may be submitted directly to the Government; in the latter case, the cover page of the subcontractor's proposal must clearly identify the proposal to which it belongs.

Biographical Sketches

Four-page limit per individual. Biographical sketches should be included for each of the key personnel listed on the budget page, including collaborating investigators and support staff. These documents are a critical component of the review process. Incomplete or missing biographical sketches may result in lower global priority scores. The Biographical Sketch form may be used. Use of this form is not mandatory, but the information requested shall be presented in a similar format.

Existing/Pending Support

Start section on a new page; no page limit. List on a separate page the titles, time commitments, supporting agencies, durations, and levels of funding for all existing and pending research projects involving the PI and key personnel. If no support exists, state "none." Proposals submitted under this program announcement should not duplicate other funded research projects.

Facilities/Equipment Description

No page limit. Describe the facilities available for performance of the proposed research/services. Describe the institutional commitment, including any additional facilities or equipment proposed for purchase or available for use at no cost to the DARPA. Indicate if government-owned facilities or equipment are proposed for use.

Provide letters of support from any collaborating individuals or institutions in this section of the proposal.
Costs proposed must conform to the following regulations and principles:

- **Commercial Firms:** Federal Acquisition Regulations (FAR) Part 31 and Defense FAR Supplement Part 31, (http://farsite.hill.af.mil), Contract Cost Principles and Procedures.

- **Educational Institutions:** Office of Management and Budget (OMB) Circular A-21, Cost Principles for Educational Institutions (http://www.whitehouse.gov/omb/grants/grants_circulars.html).
- **Nonprofit Organizations:** OMB Circular A-122, Cost Principles for Nonprofit Organizations. OMB Circular A-133, Audits of Institutions of Higher Education and Other Nonprofit Organizations (http://www.whitehouse.gov/omb/grants/grants_circulars.html).
- **State, Local, and Tribal Governments:** OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments (http://www.whitehouse.gov/omb/grants/grants_circulars.html).

C. SUBMISSION PROCESS

Offerors must submit an original (paper) proposal consisting of Volumes I and II, five (5) paper copies and an electronic copy on one of the following types of approved fixed media: a single CD-ROM; a single 100 Megabyte (MB) Iomega Zip® disk; or a single 3.5 inch High Density MS-DOS -formatted 1.44 MB diskette. The printed versions must be bound; ring binders will not be accepted. The fixed media must contain the technical proposal in MS Word or HTML format and the cost proposal in MS Excel-readable format; both must reference DARPA05-01DBAC. To be considered, proposals must be received by 1600 EST, 14 July 2005. Proposals should be mailed to Schafer Corporation, 3811 N. Fairfax, Drive, Arlington, VA 22203, ATTN: Mr. Larry Dobbs/DARPA05-01DBAC/Document Control.

D. REGULATORY REQUIREMENTS

Completed and signed copies of the "Certificate of Environmental Compliance", Appendix 8 and "Principal Investigator Safety Program Assurance", Appendix 11, form must be completed and submitted with proposal.

Do not submit other regulatory documents (Research Involving Human Subjects and/or Anatomical Substances/Cadavers; Research Involving Animals) with the proposal. Instead, the applicant should provide these documents to the USAMRMC only upon request.

E. USAMRAA REQUIRED DOCUMENTS

The most current version of the institution's negotiated "Rate Agreement," must be submitted to the US Army Medical Research Acquisition Activity at the address in Section I E prior to negotiations.

VI. PROPOSAL EVALUATION

A. EVALUATORS

It is the policy of DARPA to treat all proposals as competitive information, and to disclose the contents only for the purposes of evaluation. The Government intends to use non-Government personnel as special resources to assist with the logistics of administering the proposal evaluation and to provide selected technical assistance related to proposal evaluation. Support

personnel are restricted by their contracts from disclosing proposal information for any purpose. Contractor personnel are required to sign Organizational Conflict of Interest and/or Non-Disclosure Agreements. By submission of its proposal, each offeror agrees that proposal information may be disclosed to these selected contractors for the limited purpose stated above. Any information not intended for limited release to support contractors must be clearly marked and segregated from other submitted proposal material.

B. EVALUATION CRITERIA

Evaluation of DBAC proposals will be performed using the following criteria, which are listed in descending order of relative importance:

Scientific and technical merit
Offeror qualifications
Cost realism

Scientific and Technical Merit
The most important factor in evaluating the proposals is the scientific and technical merit of the proposed approach and its expected contribution to finding and stopping bleeding on the battlefield. The evaluation of merit includes the following specific aspects that are ranked in order of importance:

a) Technical merit and expected likelihood of success of the proposed cuff system to meet all of the specifications in Table 1 in Phase I.

b) Technical merit and probability of achievement of the performance and biophysical models planned for Phase I.

c) Technical merit and probability of achievement of the detection, localization, and coagulation algorithm development approaches.

d) Technical merit and probability of achievement of the control system approach.

e) Technical merit and probability of achievement of a cuff device and a fieldable prototype that meets the logistics specifications for weight and volume.

f) Manufacturability of the proposed device.

g) The apparent robustness and safety of the overall system proposed.

h) Clarity and soundness of proposed SOW, including completeness of plan for Phase I.

Offeror Qualifications
The next most important factor in evaluating the proposals is the demonstrated ability of the offeror's team to successfully carry out the proposed work. The evaluation includes these aspects:

a) The offeror's relevant capabilities and demonstrated experience that indicate ability to carry out the planned work.

b) The offeror's resources and facilities committed to this work, as well as agreements with outside organizations for access to necessary facilities.

c) The selection of key personnel with the skills and experience required to accomplish the tasking and their availability for the duration of the contract.

d) The offeror's experience with manufacturing similar products.

Cost Realism
Cost will be evaluated to determine whether the offeror's estimate is reasonable and realistic for the technical and management approach offered, as well as to determine the offeror's practical understanding of the effort. Cost reasonableness will be evaluated by assessing the number of labor hours and labor mix proposed as well as the reasonableness of other cost elements (e.g. travel, materials, subcontractors, etc). Cost realism will only be used as an evaluation criterion if there is reason to believe that the offeror has significantly under- or over-estimated costs to complete the effort.

VII. AWARD ADMINISTRATION INFORMATION

A. Award Notices: After the evaluation process is completed, every applicant will receive notification of the award status of his or her proposal . Applicants can expect to be notified of the agency's decision in September 2005.

B. Administrative Requirements: All awards are made to organizations, not individuals. A PI should submit a proposal through, and be employed by or affiliated with, a university, college, non-profit research institution, commercial firm, or government agency (including military laboratories) to receive support. To be eligible for an award, a prospective recipient should meet certain minimum standards pertaining to institutional support, financial resources, prior record of performance, integrity, organization, experience, operational controls, facilities, and conformance with safety and environmental statutes and regulations (OMB Circular A-110 and DOD Grant and Agreement Regulations). *Any organization requesting receipt of an award from this announcement must be registered in the Central Contractor Registration (CCR) database. Access to the CCR online registration is through the CCR homepage at* *http://www.ccr.gov.*

Any change in the institution, the PI, and/or the SOW will require that the PI resubmit contact information. Any delay in the submission of updated information could result in a delay in the contracting and regulatory review and a subsequent delay in payment.

C. Award Negotiation: Award negotiation consists of discussions, reviews, and justifications of critical issues involving the USAMRAA. A Contract Specialist and/or representative from USAMRAA will contact the Contract Representative from the Sponsored Programs Office (or equivalent) who is authorized to negotiate contracts and grants at the applicant's institution. As

part of the negotiation process, additional documentation and justifications related to the proposed SOW and associated budgets may be required.

Note that the award start date will be determined during the negotiation process.

D. Regulatory Review

1. Overview**:** Concurrent with the USAMRAA negotiation, the Office of Surety, Safety and Environmental will review the Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance form submitted with the proposal. The applicable USAMRMC regulatory office will review documents related to research involving animal use, human subjects/anatomical substance use, and cadaver use submitted upon request to ensure that Army regulations are met.

2. Certificate of Environmental Compliance**:** The Certificate of Environmental Compliance, Appendix 8 must be submitted with the proposal. If multiple research sites/institutions are funded in your proposal, then a Certificate of Environmental Compliance for each site will be requested at a later date.

3. Safety Program Documents**:** The Principal Investigator Safety Program Assurance, Appendix 11 form must be submitted with the proposal.

A Facility Safety Plan is also required and will be requested at a later date. Specific requirements for the Safety Program Plan can be found at Facility Safety Plan, Appendix 11.

If multiple research sites/institutions are funded in your proposal, then a Facility Safety Plan for each site/institution not listed in the aforementioned website will be requested at a later date.

4. Research Involving Animal Use**:** Animal use documents should not be submitted with the proposal and will be requested at a later date. Specific requirements for research involving animals can be found at Animal Use, Appendix 10

5. Research Involving Human Subjects/Anatomical Substances/Cadavers**:** (See appendices for information pertaining to the submission of human subjects and/or human anatomical substances documents or cadavers.) In addition to local Institutional Review Board (IRB) approval to conduct research involving human subjects and/or anatomical substances or cadavers, a second tier of IRB review and approval is also required by the DOD. This second review is conducted by the Human Subjects Research Review Board (HSRRB), which is administered by the USAMRMC Human Subjects Protection branch. The HSRRB is mandated to comply with specific laws and directives governing all research involving human subjects that is conducted or supported by the DOD. These laws and directives are rigorous and detailed and will require information in addition to that supplied to the local review board. For example:

- Intent to Benefit. In the development of a research protocol for submission to the DOD, the applicant must specifically address, if applicable, the Intent to Benefit. An individual not legally competent to consent (e.g., minors) may not be enrolled in DOD-sponsored research unless the research is intended to benefit each and every subject enrolled in the study. Applicants should be aware that this law makes placebo-controlled clinical trials problematic because of the 'intent to benefit' requirement whenever participation is sought of subjects from whom consent must be obtained by the legally authorized representative.
- The DOD considers cell lines of human origin to be human anatomical substances/cadavers. Use of these cell lines is subject to HSRRB review and approval.

Specific requirements for research involving human subjects, human anatomical substances,
and/or cadavers can be found at Human Use, Appendix 9
An informed consent form template can be located at Human Use, Appendix 9.

6. Award/Regulatory Approval**:** Once an award is made, the applicant may not use, employ, or subcontract for the use of any human subjects, human anatomical substances, or laboratory animals without written approval from the applicable USAMRMC regulatory office. USAMRMC will forward these written approvals directly to the applicant.

- **Fiscal Report Requirements:** Quarterly fiscal report requirements may include the Standard Form Report, SF 272, Federal Cash Transaction, used for grants and cooperative agreements to track the expenditure of funds on the research project.

E. REPORTING REQUIREMENTS

Performers will provide monthly status reports, due within two weeks of the end of each month; quarterly reports, due every quarter (at the time of the Government quarterly review, if applicable); and a final report, due at the end of each phase. The monthly status report will briefly summarize the progress of the research activities during the previous month, including major accomplishments as well as any significant difficulties that have been experienced or are expected. It will identify any aspects of the work that are ahead of or behind schedule. It will track the expenditures of funds, by month and cumulatively, and report actual or anticipated cost overruns or underruns. The quarterly reports will provide a more detailed description of all significant progress since the previous quarterly report, describing results, status, and conclusions to date. It also affords the opportunity to suggest modifications to the previously agreed upon statement of work (SOW), based on the results to date. The final report will be a cumulative, stand-alone document that describes the work of the entire phase leading up to it. Performers are also responsible for providing Scientific and Technical Reports (STARs) as applicable for their work funded under this effort, including for all: measurements taken (including the experimental methods, test conditions, and uncertainty estimates); models developed (including the underlying physical basis for the models, assumptions, and experimental data used for calibration or validation); simulation results (including a description of the models/codes used, and the conditions simulated – initial and boundary conditions); formulations developed (including the processes used to make the formulations); and

subsystems (design and prototypes). STARs are due at the end of each Phase. Specific aspects of each type of report and other deliverables are identified below.

All reports must be delivered in both print format and editable electronic format; the performer may recommend a preferred format for each deliverable, but the Government will have final approval. Quarterly and final reports will consist of both a written report and a shorter briefing to be presented orally; monthly reports will consist of only a written document (no oral presentation required).

With the exception of any financial information or other exceptions negotiated as described in Section II.C (paragraphs 5-7), all deliverables may be released to outside organizations, both Government and non-Government.

F. KEY PERSONNEL REQUIREMENT

If one or more of the key personnel, as defined in Section V.B.1., for whatever reason, becomes or is expected to become unavailable for work under this contract for a continuous period exceeding 15 work days, or is expected to devote substantially less effort to the work than indicated in the proposal, the contractor will immediately notify the DARPA PM and the Contracting Officer and, subject to the concurrence of the Contracting Officer or his authorized representative, will promptly replace such personnel with personnel of substantially equal ability and qualifications.

All requests for approval of such substitutions must be in writing and must provide a detailed explanation of the circumstances necessitating the proposed substitutions. They must contain a complete resume for the proposed substitute, and any other information requested or needed by the Contracting Officer to approve or disapprove the proposed substitute. The Contracting Officer, in collaboration with the DARPA Program Manager, will evaluate such requests and promptly notify the contractor in writing of approval or disapproval of the substitution.

If the Contracting Officer determines that suitable and timely replacement is not reasonably forthcoming for key personnel who have been reassigned, terminated, or otherwise become unavailable for the contract, or that resultant reduction of productive effort would be so substantial as to endanger successful or timely completion of the contract, then the contract may be terminated by the Contracting Officer for default or for the convenience of the Government, as appropriate. Or, if the Contracting Officer finds the contractor at fault for the condition, s/he may choose to equitably adjust downward the contract price to compensate the Government for the resultant delay, loss, or damage.

VIII. OTHER INFORMATION

A. Disclosure of Proprietary Information outside the Government: By submission of a proposal, the applicant understands that proprietary information may be disclosed outside the Government for the sole purpose of technical evaluation. The DARPA will obtain a written agreement from the evaluator that proprietary information in the proposal will only be used for evaluation purposes and will not be further disclosed or used. Funded proposals may be subject to public release under the Freedom of Information Act; proposals that are not selected for funding will not be subject to public release.

B. Government Obligation: Applicants are cautioned that only an appointed Contracting/Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government to fund preparation of a proposal or to support research should be inferred from discussions with a technical project officer. Applicants who, or organizations that, make financial or other commitments for a research effort in the absence of an actual legal obligation signed by the USAMRAA Contracting/Grants Officer do so at their own risk.

C. Title to Inventions and Patents: In accordance with the Bayh-Dole Act (35 USC 200 et seq. [1]), title to inventions and patents resulting from such federally funded research may be held by the grantee or its collaborator, but the U.S. Government shall, at a minimum, retain nonexclusive rights for the use of such inventions. An investigator must follow the instructions in the assistance agreement concerning license agreements and patents.

D. J-1 Visa Waiver: It is the responsibility of the awardee to ensure that the research staff is able to complete the work without intercession by the DOD for a J-1 Visa Waiver on behalf of a foreign national in the United States under a J-1 Visa.